



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,205	05/06/2004	Christopher E. Banas	6006-157	7254

7590 03/08/2011
ROSENBAUM & ASSOCIATES, P.C.
Suite #380
650 Dundee Road
Northbrook, IL 60062

EXAMINER

GANESAN, SUBA

ART UNIT	PAPER NUMBER
----------	--------------

3774

MAIL DATE	DELIVERY MODE
-----------	---------------

03/08/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/840,205	Applicant(s) BANAS ET AL.	
	Examiner SUBA GANESAN	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,7,9-15 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7,9-15 and 17-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 1/5/2011 have been fully considered but they are not persuasive.
2. Applicant argues that Palmaz lacks a graft where "each peak in the luminal surface is longitudinally coincident with each peak in the abluminal surface." This is not persuasive; the term "longitudinally coincident" is given its broadest reasonable interpretation consistent with the specification as 'collinear' or aligned along the same longitudinal line. Examiner notes that even without this interpretation, the rejection is based on the combination of Palmaz and Casey. Casey clearly teaches coincident peaks and valleys on the luminal and abluminal surface.
3. Applicant argues that the graft of Casey is made from non-metallic material using a mechanical or fluid force to shape the graft on a mandrel. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Palmaz teaches metallic and pseudometallic materials and fabrication techniques. Casey is relied upon as a teaching reference for a specific pattern of undulations or corrugations. A person of ordinary skill in the art, looking to the combination of Palmaz and Casey would appreciate combination of the materials and manufacturing techniques of Palmaz with the specific

pattern of Casey for the purpose of providing corrugations on a thin film graft.

Corrugations are desirable for imparting flexibility to the graft.

4. Applicant argues that Palmaz does not disclose or suggest a plurality of microperforations disposed through a wall segment disposed between longitudinally alternating radially extending peaks and valleys. Examiner disagrees. Examiner notes that the claim language “disposed through the portion of the body member between the coincident peaks and the coincident valleys” does not require exclusive positioning of the microperforations only between the peaks and valleys; rather, this language requires that *at least* the area between the peaks and valleys includes microperforations. Thus, microperforations in the entire graft still meet the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims **1, 3, 13-14, 17-18, 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) (Palmaz) in view of Casey, II et al. (Pub. No.: US 2004/0019375) (Casey).

2. Palmaz teaches an implantable medical graft, comprising: a generally tubular body member comprising a film selected from the group consisting of metallic and pseudometallic materials (page 17, lines 1-7); and at least a portion of the body member

Art Unit: 3774

having a plurality of circumferential corrugations defined by a radially undulating pattern of wall segments disposed between longitudinally alternating radially extending peaks and valleys (fig. 2 and 10, and page 5, lines 16-19, specifically: "the plurality of structural members may be arranged . . . [as] single or plural elements which form a tubular diamond-like or undulating pattern, in which adjacent structural members are spaced apart from open regions or interstices between adjacent structural members"). Palmaz further teaches luminal and abluminal interstices (fig. 7) between adjacent structural members.

However, this teaching from Palmaz is not described in sufficient detail to warrant the conclusion that Palmaz teaches continuous circumferential corrugations with radially extending peaks and valleys. Casey teaches a vascular graft structure with continuous circumferential corrugations having radially extending peaks and valleys (fig. 1 and 4B) resulting in a prosthetic graft with strong and flexible walls that has coincident peaks and valleys on the luminal and abluminal surfaces. Casey further teaches undulation-free sections (fig. 1, 4A-B). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the graft of Palmaz with areas of continuous circumferential undulations with radially extending peaks and valleys as suggested by Palmaz and specifically taught by Casey for the purpose of providing a strong and flexible graft wall. The need for flexibility is particularly relevant when designing for implantation within a curved vessel in the body or when providing a minimally invasive implantation technique. Palmaz teaches several methods of fabricating the disclosed stent/graft, including vacuum deposition and etching. It would

Art Unit: 3774

have been obvious to one of ordinary skill in the art, at the time the invention was made, to combine a thin film deposited graft with unitary structural support members as taught by Palmaz with a specific undulating pattern as taught by Casey, since doing so would be a mere modification (if any is required) of the shape of the structural members of Palmaz. Both designs arrive at the same purpose: providing a stronger graft. Such a substitution of one known equivalent pattern for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

3. Palmaz teaches microperforations disposed through the wall segments (e.g. figs. 2-3 and 8A-C, page 12 lines 1-8). Palmaz broadly teaches that the openings “may be random or may be patterned” and are preferably located in the interstitial web 24 (see fig. 2). Examiner considers the interstitial web to be a “wall segment” that is disposed between alternating peaks (midpoint of the highest region) and valleys (midpoint of the lowest region). This interpretation is consistent with the combination of Palmaz and Casey, as Casey teaches similar peak-to-valley configuration in fig. 4B. Examiner notes that the claim language “disposed through the portion of the body member between the coincident peaks and the coincident valleys” does not require exclusive positioning of the microperforations only between the peaks and valleys; rather, this language requires that *at least* the area between the peaks and valleys includes microperforations. Thus, microperforations in the entire graft (example: fig. 8C) still meet the claim.

4. Palmaz teaches non-undulating circumferential regions (see fig. 3); Casey further teaches non-undulating circumferential regions (figs. 1-5). The Palmaz stent is made of

Art Unit: 3774

a film of metallic material, including titanium, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof (pg. 17 lines 1-7).

5. With respect to claim 17, Palmaz in view of Casey teach the circumferential corrugations as claimed. The resultant combination would be fully capable of bending in excess of 180 degrees about the longitudinal axis, since Palmaz discloses thin film deposition, which results in a thin and flexible prosthesis, and Casey teaches the use of corrugations to increase flexibility (fig. 1).

6. Claims **2, 11-12, 15, 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) (hereafter, Palmaz) in view of Casey, II et al. (Pub. No.: US 2004/0019375)(hereafter, Casey) further in view of Chuter et al. (Pub. No.: US 2003/0176912)(hereafter, Chuter).

7. Palmaz in view of Casey is explained supra. Palmaz in view of Casey lacks suture openings on an end of the graft. Chuter teaches the use of openings 35 for sutures (fig. 1, for example) for the purpose of securing an end support to the graft and ultimately anchoring the prosthetic in an area with the best available tissue for anchorage. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized openings on the resultant combination device of Palmaz and Casey. A person of ordinary skill in the art would recognize that the reinforcement provided by openings 35 of Chuter would be desirable to prevent elongation or tears in the suture hole by providing a stronger location for attachment.

Art Unit: 3774

One of ordinary skill in the art would have further been motivated to provide suture openings to provide specific placement of sutures aid a surgeon in anchoring the prosthetic to a native blood vessel.

8. Chuter further teaches the use of at least one barb member 86 to provide further anchoring of the device. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the combination of Palmaz and Casey with at least one barb for the purpose of providing additional anchorage and stabilization of the device in the body. Chuter teaches at least one suture member integrally extending along a longitudinal axis of the device: see fig. 2 for example.

9. Claims **6-7, 9-10, 21-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2) (Palmaz) in view of Casey, II et al. (Pub. No.: US 2004/0019375) (Casey) and Chuter et al. (Pub. No.: US 2003/0176912) (Chuter) as applied above, further in view of Kula et al (6,325,825 B1) (Kula).

10. Palmaz in combination with Casey and Chuter teaches an implantable medical graft as above. However the combination lacks the thickness of the undulating regions as less than that of the non-undulating regions. Kula teaches an implantable medical graft having thicker ends, which correspond to the non-undulating regions of Palmaz and Casey (col. 4, lines 60-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of an implantable medical graft having thicker ends, as taught by Kula, to an implantable medical graft as per Palmaz and Casey, in order to “protect the artery and any plaque from abrasion that

Art Unit: 3774

may be caused by the stent 10 ends during insertion of the stent 10. The modification also may provide increased radio-opacity at the ends of the stent 10. Hence it may be possible to more accurately locate the stent 10 once it is in place in the body” as found in Kula (col. 4, lines 60-66).

Regarding claim 7 Palmaz and Casey in further view of Kula fail to disclose the **specific** thicknesses of the claimed regions. However, Palmaz discloses that the thickness of the microperforated material is approximately 10 micrometers (page 21, lines 13-14). Palmaz also discloses that the circumferential corrugations may be formed by a “subtractive” method (Fig. 10). The reduction of the undulation region relative to the non-undulated region would result in a thickness of the thinner region *about* 3-7 micrometers.

11. With respect to claims 9, 10, 21 and 22 Palmaz, Casey, and Kula fail to disclose the suturing openings as cruciform, generally Y-shaped slots or elongated slots with a terminal fillet. However, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to make the slots these shapes. Applicant has not disclosed that these shapes provides an advantage, is used for a particular purpose, or solve a stated problem, and therefore appear to be a matter of obvious design choice. One of ordinary skill in the art, furthermore, would have expected Applicant’s invention to perform equally well with either the holes of Chuter or the claimed slots because both allow for the passage of sutures. Furthermore such shaped holes for sutures are known in the art (Moser U.S. Pat. No. 5725556). Therefore, it would have been obvious to one

of ordinary skill in the art to modify the cited references to obtain the invention as specified in claims 9 and 10.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3774

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID ISABELLA/
Supervisory Patent Examiner, Art
Unit 3774

/S. G./
Examiner, Art Unit 3774